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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,383	10/27/2003	Ekambar R. Kandimalla	HYB-005US4	5766

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HORNING, MICHELLE S	
ART UNIT	PAPER NUMBER
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/694,383	KANDIMALLA ET AL.	
	Examiner	Art Unit	
	MICHELLE HORNING	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12 and 14-19* is/are pending in the application.

4a) Of the above claim(s) *15-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12, 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is responsive to communication (RCE) filed 12/26/2007. The status of the claims is as follows: claims 12 and 14 are under current examination, claims 1-11, 13 and 20-38 are canceled and claims 15-19 are withdrawn because they are drawn to non-elected inventions. Regarding election of species, Applicant elected the sequence set forth by SEQ ID NO: 2 in communication filed 5/10/2007.

Request for Rejoinder

Applicant has requested to rejoin the withdrawn claims 15-19 herein; however, no claim has been found allowable (MPEP 821.04(a)); see rejections below.

Response to Arguments

Applicant has amended the claims to include the following limitation: "wherein the immunostimulatory moiety is selected from the group consisting of C3-alkyl linker, 2-aminobutyl-1,3-propanediol linker, beta-L-deoxynucleoside, amino linker, nucleoside methylphophonate, 2'-O-methyl-ribonucleoside, 1', 2'-dideoxyribose, C3-linker, Spacer 18, 3'-deoxynucleoside, 2'-O-propargyl-ribonucleoside, Spacer 9 and 2'-5' linkage" (see claim 12). Of note, the sequence set forth by SEQ ID NO: 2 (elected species) consists of only nucleic acid units. The new limitations are directed to new species and do not read upon SEQ ID NO: 2. Examination will be extended to *2'-O-methyl-ribonucleoside*.

Applicant will consider taking necessary action with the respect to the double patent rejections at a later time.

Withdrawn Rejection

The double patenting rejections over 10/694, 586, 11/153, 054 and 11/270, 805 has been withdrawn due to either persuasive arguments by the Applicant or a misinterpretation of the art by the Examiner. The claims of the patent applications above are drawn to sequences of differential structures compared to that of the instant application.

Claim Rejections - 35 USC § 102-NEW

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 12 and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by US Application 11/274, 043 (PGPUB 20060142556).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

The teachings of '043 provide the sequence set forth by SEQ ID NO: 2 of the instant application; see SEQ ID NO: 1. Further, Example 1 (Modulation of

Immunostimulatory Effect *In Vitro*) provides CpG sequences containing a 2'-OMe; see paragraphs 47-48.

Claims 12 and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by US Application 10/365, 678 (PGPUB 20040092468, hereinafter as "Schwartz").

Schwartz discloses sequences in which at least one base has been substituted with a modified base and administration of said sequence modulates an immune response (see Technical Field). Paragraphs 59 and 60 further describes specific modified bases, including modified cytosines, which may be used in immunomodulatory oligonucleotides. Table 1 provides oligonucleotide sequences that meet the structural limitations of the claimed invention found in the formula of claim 1 (see page 13, SEQ ID NO: 2 by Schwartz). More specifically, the modified base used within these sequences is a 5-bromocytosine, which is adjacent to a naturally occurring guanosine while the other bases are of the naturally occurring form. Further, the sequence of SEQ ID NO: 2 contains a total of 22 nucleotides, meeting the length requirement. Paragraph 11 describes the sequences flanking the CpG as influencing the immunostimulatory activity of an oligonucleotide which meets the limitation of a potentiation domain as defined by the instant specification. Of note, the instant application defines an immunostimulatory moiety as "a chemical structure at a particular position within the immunostimulatory domain or the potentiation domain that causes the immunostimulatory oligonucleotide to be more immunostimulatory than it would be in the absence of the immunostimulatory moiety" (see paragraph 65). Disclosed examples include modifications in the phosphate

backbones, such as phosphorothioates (see paragraph 66). With respect to 2'-O-methyl-ribonucleoside, the author provides the following recitation under "Modified Bases and Base Analogs": "The oligonucleotide of the invention can comprise ribonucleotides (containing ribose as the only or principal sugar component), deoxyribonucleotides (containing deoxyribose as the principal sugar component), or, in accordance with the state of the art, modified sugars or sugar analogs can be incorporated in the modified ISS. Thus, in addition to ribose and deoxyribose, the sugar moiety can be pentose, deoxypentose, hexose, deoxyhexose, glucose, arabinose, xylose, lyxose, and a sugar "analog" cyclopentyl group. The sugar can be in pyranosyl or in a furanosyl form. In the modified ISS, the sugar moiety is preferably the furanoside of ribose, deoxyribose, arabinose or **2'-0-methylribose**, and the sugar can be attached to the respective heterocyclic bases either in .alpha. or .beta. anomeric configuration. The preparation of these sugars or sugar analogs and the respective "nucleosides" wherein such sugars or analogs are attached to a heterocyclic base (nucleic acid base) per se is known, and need not be described here, except to the extent such preparation can pertain to any specific example" (emphasis added, see paragraph 56). In conclusion, the author meets the limitations of the invention.

Double Patenting-MAINTAINED

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 12 and 14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 18 of copending Application No. 10/865, 245. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to an immunostimulatory oligonucleotide containing a CpG as well as linkers. Further, both sets of claims are very broad in scope in that they overlap in common oligonucleotides.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 12 and 14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 9, 11 and 39 of copending Application No. 10/694, 418. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to an immunostimulatory oligonucleotide containing a CpG, immunostimulatory moiety including a C3 alkyl linker and a nucleoside methylphosphonate. Further, both sets of claims are very broad in scope and they are both drawn to comparable sequence structures.

Claims 12 and 14 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 7262286. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to an immunostimulatory oligonucleotide containing a CpG formula and in which the C is an analog. Because both sets are broad in scope, they are both drawn to similar sequence structures.

Conclusion

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHELLE HORNING whose telephone number is (571)272-9036. The examiner can normally be reached on Monday-Friday 8:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michelle Horning/
Examiner, Art Unit 1648

/Bruce Campell/
Supervisory Patent Examiner, Art Unit 1648